

# Good Clinical Practice

ESIC Medical College, Faridabad

August 10 - 11, 2017

## Program Agenda

August 10, 2017 (Day 01)

Time	Title (Learning Objectives)	Presenter
09:00 – 09:30	Registration	<b>Ms. Neha Mishra</b> , Training Coordinator, CDSA
09:30 – 10:00	<ul style="list-style-type: none"> <li>Welcome Address</li> <li>Keynote Address</li> <li>Course Introduction &amp; Overview</li> <li>Vote of Thanks</li> </ul>	<ul style="list-style-type: none"> <li><b>Dr. Asim Das</b> Dean, ESIC Medical College, Faridabad</li> <li><b>Dr. Shinjini Bhatnagar</b> Dean, Clinical Research, THSTI</li> <li><b>Dr. Sucheta Banerjee Kurundkar</b> Director Training, CDSA</li> <li><b>Dr. Ranabir Pal</b> Professor &amp; Chair (Head) of Community Medicine, ESIC Medical College, Faridabad</li> </ul>
10:00 – 10:30	<b>Group Photograph &amp; Networking Tea</b>	
10:30 – 11:15	Overview of GCP <ul style="list-style-type: none"> <li>What is GCP? Why GCP?</li> <li>Principles of ICH GCP</li> <li>Addendum (R2)</li> </ul>	<b>Dr. Pawandeep Kaur Dhawan</b> Associate Medical Director, CDSA
11:15 – 12:00	Current Regulations & Guidelines in India for Clinical Trials	<b>Shri. A. B. Ramteke</b> Former Joint Drugs Controller (India), CDSCO, HQ, New Delhi; Consultant, Regulatory Affairs, CDSA
12:00 – 13:30	Ethical Considerations <ul style="list-style-type: none"> <li>EC Functioning</li> <li>Informed Consent Process</li> <li>Confidentiality and Privacy</li> <li>Vulnerable Population</li> </ul>	<b>Dr. Nandini K. Kumar</b> Former Deputy Director General (Sr. Grade), ICMR, Dr. TMA Pai Endowment Chair, Manipal University; Adjunct Faculty, CDSA
13:30 – 14:15	<b>Lunch Break</b>	
14:15 – 15:00	Clinical Trial Documents	<b>Dr. Pawandeep Kaur Dhawan</b> Associate Medical Director, CDSA
15:00 – 15:45	Roles and Responsibilities of Sponsor and Institution	<b>Mr. Anirban Roy Chowdhury</b> Senior Director, Global Clinical Trial Operations, MSD Pharmaceuticals (Merck).
15:45 – 16:00	<b>Tea/Coffee Break</b>	
16:00 – 16:45	Roles and Responsibilities of Monitor	<b>Dr. Monika Bahl</b> Director Clinical Portfolio Management, CDSA
16:45 – 17:45	Exercises, Case studies, Group activities	All Faculty
>17:45	Open Forum for Q & A	

### August 11, 2017 (Day 02)

Time	Title (Learning Objectives)	Presenter
09:00 – 09:30	Recap	Participants
09:30 – 10:15	Roles and Responsibilities of an Investigator	<b>Dr. Ranabir Pal</b> Professor & Chair (Head) of Community Medicine, ESIC Medical College & Hospital, Faridabad
10:15 – 10:30	<b>Tea/Coffee Break</b>	
10:30 – 11:15	Data Handling & Record Keeping	<b>Dr. Monika Bahl</b> Director Clinical Portfolio Management, CDSA
11:15 – 12:00	Quality Assurance	<b>Dr. Sucheta Banerjee Kurundkar</b> Director Training, CDSA
12:00 – 12:45	GCP: Special Concerns	<b>Dr. N. R. Biswas</b> Director & Vice Chancellor, IGIMS, Patna
12:45 – 13:30	<b>Lunch Break</b>	
13:30 – 15:30	Exercises, Case studies, Group activities	All Faculty
	<b>Tea/Coffee Break</b>	
15:30 – 16:30	Exit Assessment	
>16:30	Open Forum for Q & A and Feedback Distribution of Certificates	

**Happy Learning!!**